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(54) Title: SEPTAL OCCLUDER AND ASSOCIATED METHODS

(57) Abstract: Devices are provided for closing septal defects such as PFOs. The devices generally include a proximal anchor member, a distal anchor member, and a flexible center joint connecting the two anchor members.

SEPTAL OCCLUDER AND ASSOCIATED METHODS

Related Application

The present application is based on and claims priority from U.S. Provisional Patent Application Serial No. 60/340,858 filed on December 19, 2001 and entitled PATENT FORAMEN OVALE (PFO) CLOSURE DEVICE WITH BIORESORBABLE COMPONENTS.

Background of the Invention

A patent foramen ovale (PFO) as shown in FIGURE 1 is a persistent, one-way, usually flap-like opening in the wall between the right atrium 10 and left atrium 12 of the heart. Since left atrial (LA) pressure is normally higher than right atrial (RA) pressure, the flap typically stays closed. Under certain conditions, however, RA pressure can exceed LA pressure creating the possibility for right to left shunting that can allow blood clots to enter the systemic circulation. In utero, the foramen ovale serves as a physiologic conduit for right-to-left shunting. After birth, with the establishment of pulmonary circulation, the increased left atrial blood flow and pressure results in functional closure of the foramen ovale. This functional closure is subsequently followed by anatomical closure of the two over-lapping layers of tissue: septum primum 14 and septum secundum 16. However, a probe-patent foramen ovale has been shown to persist in up to 35% of adults in an autopsy series. Using contrast echocardiography (TEE), a PFO can be detected in approximately 25% of adults. These numbers are different because an autopsy allows direct visual inspection of the anatomy, whereas contrast echocardiography relies on the measurement of an indirect physiologic phenomenon.

The cause of ischemic stroke remains cryptogenic (of unknown origin) in approximately 40% of cases. Especially in young patients, paradoxical

embolism via a PFO is considered in the diagnosis. While there is currently no proof for a cause-effect relationship, many studies have confirmed a strong association between the presence of a PFO and the risk for paradoxical embolism or stroke. In addition, there is good evidence that patients with PFO and paradoxical embolism are at increased risk for future, recurrent cerebrovascular events.

The presence of PFO has no therapeutic consequence in otherwise healthy adults. In contrast, patients suffering a stroke or TIA in the presence of a PFO and without another cause of ischemic stroke are considered for prophylactic medical therapy to reduce the risk of a recurrent embolic event. These patients are commonly treated with oral anticoagulants, which have the potential for adverse side effects such as hemorrhaging, hematoma, and interactions with a variety of other drugs. In certain cases, such as when anticoagulation is contraindicated, surgery may be used to close a PFO. To suture a PFO closed requires attachment of septum secundum to septum primum with a continuous stitch, which is the common way a surgeon shuts the PFO under direct visualization.

Non-surgical closure of PFOs has become possible with the advent of umbrella-like devices and a variety of other similar mechanical closure designs developed initially for percutaneous closure of atrial septal defects (ASD). These devices allow patients to avoid the potential side effects often associated with anticoagulation therapies.

Brief Summary of Embodiments of the Invention

Various embodiments of the present invention are directed to devices for closing septal defects such as PFOs. The closure devices generally include a proximal anchor member, a distal anchor member, and a flexible center joint connecting the two anchor members. The center joint can be a suture. Alternatively, the center joint can be a flexible elastomeric layer, which can, e.g., be used to promote tissue ingrowth or for drug delivery. The flexible material can also be covered with a biocompatible glue to promote adherence to tissue or growth factors to accelerate tissue ingrowth.

In accordance with some embodiments of the invention, the closure device is formed of bioresorbable components such that substantially no permanent foreign body remains in the defect.

In accordance with further embodiments of the invention, mechanisms are provided to collapse the closure device for facilitating device delivery, removal and/or repositioning.

These and other features will become readily apparent from the following detailed description wherein embodiments of the invention are shown and described by way of illustration. As will be realized, the invention is capable of other and different embodiments and its several details may be capable of modifications in various respects, all without departing from the invention. Accordingly, the drawings and description are to be regarded as illustrative in nature and not in a restrictive or limiting sense.

Brief Description of the Drawings

FIGURE 1 is a cross-sectional view of a portion of the heart illustrating a PFO;

FIGURE 2 illustrates a deployed PFO closure device with bioresorbable components in accordance with one or more embodiments of the invention;

FIGURE 3 illustrates the PFO closure device of FIGURE 2 in a collapsed state for passage through a delivery catheter or sheath;

FIGURE 4 illustrates a closure device deployed to close a PFO in accordance with one or more further embodiments of the invention;

FIGURE 5 illustrates a closure device deployed to close the PFO in accordance with one or more further embodiments of the invention;

FIGURES 6A and 6B are front and side views, respectively, of a PFO closure device in accordance with one or more further embodiments of the invention;

FIGURES 7A and 7B are front and side views, respectively, of a PFO closure device in accordance with one or more further embodiments of the invention;

FIGURES 8A and 8B are side and front views, respectively, of the PFO closure device of FIGURE 6 deployed to close a PFO;

FIGURES 9A illustrates a closure device having a retrieval mechanism in accordance with one or more further embodiments of the invention in a

collapsed state for passage through a catheter or sheath;

FIGURE 9B is a front view of the FIGURE 9A device;

FIGURES 9C-E illustrate deployment of the FIGURE 9A device;

FIGURES 9F-H illustrate removal of the FIGURE 9A device;

FIGURE 10A illustrates a closure device having a retrieval mechanism in accordance with one or more further embodiments of the invention in a collapsed state for passage through a catheter or sheath;

FIGURE 10B is a front view of the FIGURE 10A device;

FIGURES 11A and 11B illustrate an anchor member with an elastic hinge in accordance with one or more further embodiments of the invention;

FIGURE 12 illustrates a PFO closure device made from a single material in accordance with one or more further embodiments of the invention;

FIGURE 13 illustrates a PFO closure device having inflatable anchor members in accordance with one or more further embodiments of the invention;

FIGURE 14 illustrates a PFO closure device with a wire connecting the proximal and distal anchor members in accordance with one or more further embodiments of the invention;

FIGURE 15 illustrates a PFO closure device having a frame member in accordance with one or more further embodiments of the invention;

FIGURE 16 illustrates a PFO closure device having frame anchor members in accordance with one or more further embodiments of the invention;

FIGURE 17 illustrates a PFO closure device having frame anchor members in accordance with one or more further embodiments of the invention;

FIGURE 18 illustrates the FIGURE 17 device in a collapsed state for passage through a catheter or sheath;

FIGURE 19 illustrates a frame anchor member having metal and polymer components in accordance with one or more further embodiments of the invention;

FIGURES 20A and 20B illustrate a PFO closure device having anchor members formed from a rolled material in accordance with one or more further embodiments of the invention in rolled and unrolled positions, respectively;

FIGURES 21A and 21B illustrate an alternate PFO closure device having anchor members formed from a rolled material in accordance with one or more further embodiments of the invention in rolled and unrolled positions, respectively;

FIGURES 22A illustrates a closure device having frame anchor members and a generally "X" shaped joint member in accordance with one or more further embodiments of the invention;

FIGURE 22B illustrates the proximal anchor member of the FIGURE 22A device;

FIGURE 22C illustrates the FIGURE 22A device in a deployed state;

FIGURES 23 illustrates a closure device having frame anchor members having a generally "+" shaped frame structure in accordance with one or more further embodiments of the invention; and

FIGURES 24 illustrates a closure device having frame anchor members having a generally "G" shaped frame structure in accordance with one or more further embodiments of the invention.

Detailed Description of Embodiments

Various embodiments of the present invention are directed to methods and devices for closing septal defects such as PFOs, primarily by eliciting a healing response at the defect.

As shown in FIGURE 2, a PFO closure device 18 in accordance with one or more embodiments of the present invention includes a distal anchor component or member 20 (which can be placed on the left atrial side of the PFO), a proximal anchor member 22 (to fix the device in place), a proximal attachment point 24 (for attachment and release from a catheter), and a central connecting member 26 (which can, e.g., be a simple suture in accordance with this embodiment).

In some embodiments, the distal anchor, the proximal anchor, and the connecting member are bioresorbable. These components can be fabricated from either a single bioresorbable polymer or by a laminated composite of two or more materials to provide a unique mix of properties such as, e.g., anchor members having stiff centers and flexible edges, and blood contacting surfaces having controlled porosity or surface texture to promote fast and thorough endothelialization, while minimizing thrombosis. In addition, the tissue contacting surface of the anchors can be designed to provide added stability by, e.g., being roughened.

The distal anchor 20 is an elongated, preferably generally cylindrical, thin bar-like member with rounded, arcuately shaped ends. The tissue contacting surface of the anchor can be generally flattened to increase tissue surface contact. In size, the distal anchor component might, e.g., be 15-30 mm long and 2 mm in diameter with a circular cross-section. The proximal anchor 22 can be of similar dimensions and shape, although it can be shorter in overall length.

Other distal and proximal anchor structures are also possible. For example, the anchors can be formed of a generally flat material rolled to form a cylindrical shape as described below with respect to the embodiments of FIGURES 20 and 21.

For delivery and deployment, the distal anchor 20 and proximal anchor 22 are positioned to be generally aligned in a longitudinal, end-to-end manner within a delivery sheath or catheter 28 as shown in FIGURE 3. These components, with the flexible connecting member 26 traverse the catheter or delivery sheath in this longitudinal orientation. The catheter or delivery sheath is inserted between septum primum and septum secundum into the left atrium 18, and the distal anchor component 20 is ejected. Then, the catheter or delivery sheath 28 is withdrawn into the right atrium, and the proximal anchor 22 is ejected. The flexible central connecting member 26 extends between septum primum and septum secundum to join the distal anchor 20 and the proximal anchor 22. Once ejected, the distal anchor and proximal anchor generally self-orientate to be essentially perpendicular to the axis of the central connecting member and in generally parallel planes to one another. The exact orientation will be governed by the individual patient anatomy.

An alternate delivery method for this device can be to deploy it directly through the septum primum as opposed to through the PFO.

The method of attaching the central connecting member 26 to the anchor and stop mechanism 22 to permit the distal anchor and the proximal anchor to be drawn together could be, e.g., via a friction fit or via a slip knot on the central connecting member. If a slip knot is used, the free end of the suture proximal to the knot can be held remotely and released after the knot has been placed in the appropriate location.

In one or more alternate embodiments of the invention shown in FIGURE 4, the central connecting member 26 is mounted to permit free sliding movement of the proximal anchor 22 relative to the central connecting member 26. A biasing spring 30, which may be an expandable coil spring, can be formed at the outer end of the central connecting member 26 to bias the proximal anchor toward the distal anchor when both are deployed from the catheter or sheath.

In the embodiments illustrated in FIGURES 4 and 5, a metallic component may be used as the central connecting member 26 in order to provide an appropriate stop and apply compression force to the proximal anchor 22. The metallic component could be a piece of shape memory wire that has one end molded or laminated into the distal anchor component 20. In FIGURE 4, the proximal anchor 22 slides on the central connecting member 26, and once it is deployed, the biasing spring 30 formed on the end of the shape memory wire expands to bias the proximal anchor 22 toward the distal anchor 20.

In the FIGURE 5 embodiment, a shape memory wire forms a hook type anchor 32 made from two wires that exit through the center of the proximate anchor and curve in opposite directions when expanded to draw the proximate anchor toward the distal anchor.

While the embodiments of FIGURES 4 and 5 can leave a permanent foreign body when the bioresorbable components dissolve (if, e.g., a metallic component is used as the central connecting member 26), one advantage of these devices is that no thrombogenic tissue scaffold (usually a vascular material) is placed on the left atrial side. Thrombus forming on the LA side of a PFO closure device can be released into the systemic circulation causing an embolic event within the coronary arteries, cerebral circulation, or distally in the vasculature, and most vascular graft materials utilized to close PFOs are

highly thrombogenic.

The PFO closure devices may need to be capable of x-ray visualization and use with radiopaque fillers or marker bands fabricated from noble metals such as platinum or gold. These markers can be attached using a variety of common methods such as, e.g., adhesive bonding, lamination between two layers of polymer, or vapor deposition.

FIGURES 6A and 6B illustrate a closure device 50 in accordance with one or more further embodiments of the invention. The device 50 includes proximal and distal anchor members 52, 54 connected with a flexible (and preferably stretchable elastomeric) center joint or connecting element 56. The anchor members 52, 54 are preferably cylindrical in shape with rounded ends. In size, the distal anchor member 54 might, e.g., be about 15-30 mm long and about 2 mm in diameter with a circular cross-section. The proximal anchor 52 can be of similar dimensions and shape, although it can be shorter in overall length. The anchor members 52, 54 are preferably made from a rigid (preferably bioresorbable) polymer (regular or shape memory), or biological tissue. Biocompatible metal can also be used.

Other distal and proximal anchor structures are also possible. For example, the anchors can be formed of a generally flat material rolled to form a cylindrical shape as described below with respect to the embodiments of FIGURES 20 and 21.

The center joint 56 of the FIGURE 6 device (as well as the center joints of the devices shown in FIGURES 7-10, 12-18, and 21 -24) are preferably elastomeric and resilient and are made from thrombogenic or inflammatory materials including, e.g., polyester, biological tissue, bioresorbable polymer, small diameter springs (e.g., Nitinol), or spongy polymeric material. Alternatively, the center joint can be made of multiple strands of material 58

such as, e.g., polymer fibers as shown in the closure device 60 of FIGURES 7A and 7B. The center joint can be textured, porous or in a form of a single or double-sided hook material such as Velcro. These kinds of surfaces produce inflammatory responses and therefore, promote faster tissue ingrowth and faster defect closure. The entire device or parts of it can be made from bioresorbable polymers.

FIGURE 8A and 8B are front and side views, respectively, of the device 50 in a PFO defect. The proximal and distal anchor members 54, 52 are longer than the defect width, thereby inhibiting the device from being embolized.

In accordance with further embodiments of the invention, a closure device can include a delivery/removal mechanism to facilitate device delivery, removal or repositioning. A device 70 shown in FIGURES 9A and 9B includes a removal string 72 and a delivery string 74. The removal string is movably secured and slides freely inside of the proximal anchor member 76. The string extends from one end of the proximal member 76 and is fixed to an opposite end of the distal anchor member 78. By pulling on the free end of the removal string 72, the whole device 70 can be collapsed and pulled into the delivery sheath 79 as shown in FIGURE 9A. The strings can, e.g., be sutures or wires such as Nitinol wire.

The delivery and removal strings are manipulated separately in order to deploy or remove the device. FIGURES 9C-E illustrate device deployment using the delivery string 74, which is preferably attached generally to the center of the proximal anchor member 76. The delivery sheath 79 containing the device 70 is first inserted between the septum primum and septum secundum into the left atrium as shown in FIGURE 9C. As shown in FIGURE 9D, the distal anchor 78 is then ejected from the delivery catheter 79. Tension is then applied to the delivery string 74, and the delivery sheath is withdrawn

into the right atrium and the proximal anchor 76 is ejected. Applying tension to the delivery string enables the proximal anchor 76 to be properly deployed in the right atrium, and keeps the anchor 76 from being ejected into the left atrium. Upon successful deployment of the device 70, both strings are released and the delivery system is withdrawn. No tension is applied to the removal string during delivery.

FIGURES 9F-H illustrate removal of the device 70. As shown in FIGURE 9F, tension is applied to the removal string, while the delivery sheath 79 is moved toward the device 70. The applied tension causes the proximal anchor 76 to be withdrawn into the delivery sheath as shown in FIGURE 9G. The distal anchor 78 is also withdrawn into the delivery sheath as further tension is applied to the removal string. The device can then be redeployed if desired or removed.

Alternatively, the delivery string 74 can be omitted, and the removal string 72 be used for both device deployment and removal. The delivery sheath 79 containing the closure device is first inserted between the septum primum and septum secundum into the left atrium in a similar manner to that shown in FIGURE 9C. The distal anchor 78 is then ejected from the delivery catheter 79 in a similar manner to that shown in FIGURE 9D. Tension is applied to the removal string 72, and the delivery sheath is withdrawn into the right atrium, and the proximal anchor 76 is ejected. Applying tension to the removal string enables the proximal anchor 76 to be properly deployed in the right atrium, and keeps the proximal anchor 76 from being ejected into the left atrium. The elasticity of the center joint connecting the anchor members helps properly position the proximal anchor at the defect. Upon successful deployment of the closure device, the string 72 is released and the delivery system is withdrawn.

As shown in FIGURES 10A and 10B, in another embodiment, strings 80

(suture, Nitinol wire, etc.) are attached to both ends of the proximal anchor member 82 of a closure device 84. Both anchor members are flexible and can fold as shown in FIGURE 10A in order to be delivered to or removed from the defect.

In accordance with a further embodiment of the invention, as shown in FIGURES 11A and 11B, each of the proximal and distal anchor members can include two elements 90 separated by an elastic hinge 92. The elastic hinge 92 can facilitate folding of the members as shown in FIGURE 11B. The hinge 92 can be molded or made from a material such as, e.g., Nitinol or other shape memory materials, which can be a different material from the elements 90.

In accordance with some embodiments of the invention, an entire closure device can be made from a single sheet of a material as shown, e.g., in the closure device 100 of FIGURE 12. Two opposite ends of the sheet can be rolled to form the proximal and distal anchor members. Glue or heat bonding can be used to maintain the rolled-up configuration of the anchor members 102, 104.

As shown in FIGURE 13, in accordance with some further embodiments of the invention, one or both anchor members 110, 112 of a closure device 114 can be inflatable. The anchor members can be inflated with, e.g., saline or other physiological fluid during or before the delivery of the device. A tube 116 can communicate with cavities in the anchor members. An inlet 118 can be provided at one of the members for introducing fluid therein.

In accordance with some further embodiments of the invention, a wire 120 such as, e.g., an S-shaped wire, can be provided to connect the proximal and distal anchor members 122, 124 of a device 126 as shown in FIGURE 14. The wire can be used to provide additional clamping force while the device is

in a PFO defect. Other wire shapes are also possible.

In accordance with further embodiments of the invention, one or more frame structures can be used as the anchor members of a closure device. For example, FIGURE 15 shows a closure device 130 having a frame structure 132. Also, FIGURE 16 shows a closure device 136 having frames 138, 139. The frames can be, e.g., a metal (e.g., Nitinol wire) or polymer frame.

FIGURES 17-19 illustrate closure devices in accordance with some further embodiments of the invention. A closure device 140 shown in FIGURE 17 includes anchor members 142, 144 having a frame structure. The frame shape can be polygonal as shown in the figure or it can alternatively be a circular shape. Other frame shapes are also possible as, e.g., will be described below with respect to FIGURES 22-24.

A recovery suture can be attached to opposite ends of the proximate anchor member 142 to collapse the anchors for delivery in a catheter 146 as shown in FIGURE 18 or for retrieval or repositioning. The anchor members can be made from a metal, preferably Nitinol, or polymers. Alternatively, as shown in FIGURE 19, an anchor member 148 can include both metal and polymer components.

In accordance with one or more further embodiments of the invention, the distal and proximal anchors can be formed of a flat sheet-like member rolled to form a cylindrical shape as shown, e.g., in the device 170 of FIGURE 20A. The anchors 172, 174 can unroll to form sheet-like members when deployed as shown generally in FIGURE 20B. The sheet-like member can be made of a material having shape memory properties such as, e.g., shape memory polymeric materials. Alternately, the sheet-like member can include metal struts made of shape memory metals such as, e.g., Nitinol or Nitinol alloys. The shape memory materials allow the device to be delivered in a

delivery sheath or catheter with the anchors in the rolled configuration of FIGURE 20A. The anchors attain the sheet-like geometry of FIGURE 20B once deployed due to their shape memory properties. The anchor members 172, 174 can be connected to each other with a connecting member 176, which can, e.g., be a suture similar to that used in the FIGURE 2 device.

FIGURES 21A and 21B illustrate a closure device 180 having rolled anchor members 182, 184, which are similar to the anchor members 172, 174 of the device of FIGURES 20A and 20B. The anchors 182, 184 are connected to each other by a connecting member or joint 186, which can be a sheet of flexible material similar to the connecting members previously described with respect to FIGURES 6 and 7.

FIGURE 22A illustrates a closure device 200 in accordance with one or more further embodiments of the invention. The device 200 includes distal and proximal anchor members 202, 204, each of which has a polygonal or circular frame structure. The anchor members are connected by a connecting member 206, which can be made from a flexible material similar to that previously described in connection with FIGURES 6 and 7. The connecting member 206 can be made of two sheets of flexible material connected at their centers, generally forming an "X" shape in the side view of the device. As shown in FIGURE 22B, the proximal anchor member 204 can include one or more recovery wires or sutures attached to the frame structure for use in device deployment of recovery. FIGURE 22C illustrates the device 200 as deployed.

FIGURES 23 and 24 illustrate closure devices 220, 230, respectively, in accordance with further embodiments of the invention. Each device 220, 230 includes distal and proximal anchor members having a frame structure. The anchor members are connected by a flexible joint 222, which can be made from a flexible material similar to that previously described in connection

with FIGURES 6 and 7. The FIGURE 23 device 220 includes distal and proximal anchor members 224, 226 generally having a "+" shape. The FIGURE 24 device 230 includes distal and proximal anchor members 232, 234 generally having a "G" shape.

The closure devices described herein can optionally be used along with suturing or stapling techniques where the anchors or flexible joints of the devices can be sewn or stapled to septum primum or secundum for better dislodgment resistance. Also, the flexible joint can, if desired, be covered with biocompatible glue to adhere to the tissue or can be loaded with drugs or growth factors to promote healing. The glue and also certain drugs can also optionally be stored in any cavities in the anchor members (e.g., in the cylindrical members of FIGURES 6 and 7) and released after deployment. Noble metal markers can also be attached to the closure devices for a better x-ray visualization.

The various closure devices described herein can include a number of advantageous features. The closure devices preferably have an atraumatic shape to reduce trauma during deployment or removal. In addition, the devices can be self-orienting for ease of deployment. Furthermore, because of the flexible center joint, the devices generally conform to the anatomy instead of the anatomy conforming to the devices, which is especially useful in long tunnel defects. In addition, the devices can preferably be repositioned or/and removed during delivery. The devices also generally have a relatively small profile after deployment. The flexible center joint of the devices can encourage faster tissue ingrowth and therefore, faster defect closure. Furthermore, there are generally no exposed thrombogenic components on the left and right atrial sides. The devices can also advantageously include bioresorbable components, which can disappear over time.

Other benefits of the devices can include possible use of a relatively

small diameter delivery sheath, use of reduced or no metal mass in the device, ease of manufacturing, cost effectiveness, and overall design simplicity.

Having described preferred embodiments of the present invention, it should be apparent that modifications can be made without departing from the spirit and scope of the invention.

Claims

1. A septal occluder, comprising:

a proximal anchor member for deployment proximate a first end of a septal defect;

a distal anchor member for deployment proximate a second end of said septal defect; and

a flexible connection member connecting said proximal and distal anchor members,

said proximal and distal anchor members and said connection member comprising bioresorbable materials.

2. The septal occluder of Claim 1 wherein said proximal and distal anchor members are elongated.

3. The septal occluder of Claim 1 wherein said proximal and distal anchor members each have a generally cylindrical shape with rounded ends.

4. The septal occluder of Claim 1 wherein a side of each anchor member for contacting a tissue surface is generally flattened to increase surface contact.

5. The septal occluder of Claim 1 wherein said proximal and distal anchor members each comprise a cylindrical structure formed by rolling a layer of material.

6. The septal occluder of Claim 1 wherein said proximal and distal anchor members are inflatable.

7. The septal occluder of Claim 1 wherein said septal occluder is collapsible for passage through a catheter or sheath.

8. The septal occluder of Claim 7 wherein said occluder can be collapsed with the proximal and distal anchor members being in a generally aligned, end to end arrangement for passage through a catheter or sheath.

9. The septal occluder of Claim 1 wherein said proximal and distal anchor members are collapsible for deployment or removal.

10. The septal occluder of Claim 9 wherein the proximal and distal anchor members are generally foldable.

11. The septal occluder of Claim 10 wherein each anchor member includes two elements separated by an elastic hinge.

12. The septal occluder of Claim 1 further comprising a removal string attached to the septal occluder to facilitate removal of the septal occluder from the septal defect.

13. The septal occluder of Claim 12 wherein said removal string is slidingly mounted in said proximal anchor member and attached to said distal anchor member.

14. The septal occluder of Claim 12 wherein said removal string is mounted to slide through said proximal anchor member.

15. The septal occluder of Claim 12 further comprising a delivery string to facilitate deployment of the septal occluder at the septal defect.

16. The septal occluder of Claim 1 wherein said septal occluder is formed from a layer of material having opposite ends rolled to form the proximal and distal anchor members.

17. The septal occluder of Claim 1 further comprising a wire connecting said proximal and distal anchor members to provide clamping force to close the defect.

18. The septal occluder of Claim 17 wherein said wire has a

serpentine configuration.

19. The septal occluder of Claim 1 wherein said connecting member comprises a suture.

20. The septal occluder of Claim 1 wherein said connecting member comprises a layer of flexible, elastomeric material.

21. The septal occluder of Claim 1 wherein said connecting member comprises a layer of flexible material made from thrombogenic or inflammatory materials.

22. The septal occluder of Claim 1 wherein said connecting member comprises a layer of flexible material that is porous or textured.

23. The septal occluder of Claim 1 wherein said connecting member comprises a layer of flexible material that is covered with a biocompatible glue to promote adherence to tissue

24. The septal occluder of Claim 1 wherein said connecting member comprises a layer of flexible material that is covered with growth factors to accelerate tissue ingrowth.

25. A septal defect closure device, comprising:

a proximal anchor member having a generally cylindrical shape for deployment proximate a first end of a septal defect;

a distal anchor member having a generally cylindrical shape for deployment proximate a second end of said septal defect; and

a suture connecting said proximal and distal anchor members.

26. The device of Claim 25 wherein said suture is slidingly mounted on said proximal anchor member.

27. The device of Claim 26 wherein said suture includes a biasing

spring at one end thereof to bias the proximal and distal anchor members toward each other when the device is deployed.

28. The device of Claim 25 wherein the suture comprises a shape memory wire.

29. The device of Claim 25 wherein said suture comprises a resilient elastomeric material.

30. The device of Claim 25 wherein a side of each anchor member for contacting a tissue surface is generally flattened to increase surface contact.

31. The device of Claim 25 wherein said proximal and distal anchor members each comprise a cylindrical structure formed by rolling a layer of material.

32. The device of Claim 25 wherein said proximal and distal anchor members are inflatable.

33. The device of Claim 25 wherein said device is collapsible for passage through a catheter or sheath.

34. The device of Claim 33 wherein said device can be collapsed with the proximal and distal anchor members being in a generally aligned, end to end arrangement for passage through a catheter or sheath.

35. The device of Claim 25 wherein said proximal and distal anchor members are collapsible for deployment or removal.

36. The device of Claim 35 wherein the proximal and distal anchor members are generally foldable.

37. The device of Claim 36 wherein each anchor member includes two elements separated by an elastic hinge.

38. The device of Claim 25 further comprising a removal string attached to the device to facilitate removal of the device from the septal defect.

39. The device of Claim 38 wherein said removal string is slidingly mounted in said proximal anchor member and attached to said distal anchor member.

40. The device of Claim 38 wherein said removal string is mounted to slide through said proximal anchor member.

41. The device of Claim 38 further comprising a delivery string to facilitate deployment of the device at the septal defect.

42. The device of Claim 25 further comprising a wire connecting said proximal and distal anchor members to provide clamping force to close the defect.

43. The device of Claim 42 wherein said wire has a serpentine configuration.

44. A septal defect closure device, comprising:

an elongated proximal anchor member for deployment proximate a first end of a septal defect;

an elongated distal anchor member for deployment proximate a second end of said septal defect; and

a flexible layer connecting said proximal and distal anchor members.

45. The device of Claim 44 wherein flexible layer comprises thrombogenic or inflammatory materials.

46. The device of Claim 44 wherein said flexible layer is porous or textured.

47. The device of Claim 44 wherein said flexible layer is covered with a biocompatible glue to promote adherence to tissue.

48. The device of Claim 44 wherein said flexible layer is covered with growth factors to accelerate tissue ingrowth.

49. The device of Claim 44 wherein said flexible layer comprises a resilient elastomeric material.

50. The device of Claim 44 wherein said flexible layer comprises a plurality of fibers connecting the anchor members.

51. The device of Claim 44 wherein said proximal and distal anchor members each have a generally cylindrical shape with rounded ends.

52. The device of Claim 44 wherein a side of each anchor member for contacting a tissue surface is generally flattened to increase surface contact.

53. The device of Claim 44 wherein said proximal and distal anchor members each comprise a cylindrical structure formed by rolling a layer of material.

54. The device of Claim 44 wherein said proximal and distal anchor members are inflatable.

55. The device of Claim 44 wherein said device is collapsible for passage through a catheter or sheath.

56. The device of Claim 55 wherein said occluder can be collapsed with the proximal and distal anchor members being in a generally aligned, end to end arrangement for passage through a catheter or sheath.

57. The device of Claim 44 wherein said proximal and distal anchor members are collapsible for deployment or removal.

58. The device of Claim 57 wherein the proximal and distal anchor members are generally foldable.

59. The device of Claim 58 wherein each anchor member includes two elements separated by an elastic hinge.

60. The device of Claim 44 further comprising a removal string attached to the device to facilitate removal of the device from the septal defect.

61. The device of Claim 60 wherein said removal string is slidingly mounted in said proximal anchor member and attached to said distal anchor member.

62. The device of Claim 60 wherein said removal string is mounted to slide through said proximal anchor member.

63. The device of Claim 60 further comprising a delivery string to facilitate deployment of the device at the septal defect.

64. The device of Claim 44 wherein said device is formed from a layer of material having opposite ends rolled to form the proximal and distal anchor members.

65. The device of Claim 44 further comprising a wire connecting said proximal and distal anchor members to provide clamping force to close the defect.

66. The device of Claim 65 wherein said wire has a serpentine configuration.

67. A septal defect closure device, comprising:

a proximal anchor member for deployment proximate a first end of a septal defect;

a distal anchor member for deployment proximate a second end of said septal defect;

a flexible connection member connecting said proximal and distal anchor members; and

a removal string extending from said proximal anchor member to facilitate collapsing and removal of the device from the septal defect.

68. The device of Claim 67 wherein said removal string is slidingly mounted in said proximal anchor member and attached to said distal anchor member.

69. The device of Claim 67 wherein said removal string is mounted to slide through said proximal anchor member.

70. The device of Claim 67 further comprising a delivery string to facilitate deployment of the device at the septal defect.

71. The device of Claim 67 wherein said proximal and distal anchor members are collapsible for deployment or removal.

72. The device of Claim 71 wherein the proximal and distal anchor members are generally foldable.

73. The device of Claim 72 wherein each anchor member includes two elements separated by an elastic hinge.

74. The device of Claim 67 further comprising a removal string attached to the device to facilitate removal of the device from the septal defect.

75. The device of Claim 74 wherein said removal string is slidingly mounted in said proximal anchor member and attached to said distal anchor member.

76. The device of Claim 74 wherein said removal string is mounted to slide through said proximal anchor member.

77. The device of Claim 74 further comprising a delivery string to facilitate deployment of the device at the septal defect.

78. A method of retrieving a deployed septal closure device having a proximal anchor member positioned proximate a first end of a septal defect, a distal anchor member for positioned proximate a second end of said septal defect, and a flexible connection member connecting said proximal and distal anchor members, said method comprising:

moving a sheath toward the proximal anchor member;

applying tension to the proximal anchor member to first withdraw the proximal anchor member into the sheath and then to withdraw the distal anchor member into the sheath;

wherein the proximal and distal anchor members are generally in an end to end, aligned arrangement in said sheath.

79. The method of Claim 78 further comprising moving the sheath toward the distal anchor member prior to withdrawing the distal anchor member into the sheath.

80. The method of Claim 78 wherein applying tension to the proximal anchor member comprises pulling a string attached to the proximal member.

81. The method of Claim 80 wherein said string is slidingly mounted in said proximal anchor member and is attached to said distal anchor member.

82. A septal defect closure device, comprising:

a proximal anchor member having a frame structure for deployment

proximate a first end of a septal defect;

a distal anchor member having a frame structure for deployment proximate a second end of said septal defect; and

a flexible joint connecting said proximal and distal anchor members.

83. The device of Claim 82 wherein said flexible joint comprises a layer of thrombogenic or inflammatory material.

84. The device of Claim 82 wherein said flexible joint comprises a plurality of fibers connecting said anchor members.

85. The device of Claim 82 wherein said flexible joint is porous or textured.

86. The device of Claim 82 wherein said flexible joint comprises a resilient elastomeric material.

87. The device of Claim 82 wherein said flexible joint comprises two layers of flexible material joined to each other generally at centers thereof.

88. The device of Claim 82 wherein said anchor members each have a frame structure having a polygonal or circular structure.

89. The device of Claim 82 wherein said anchor members each have a frame structure having a generally "+" shaped structure.

90. The device of Claim 82 wherein said anchor members each have a frame structure having a generally "G" shaped structure.

91. The device of Claim 82 wherein said anchor members each have a collapsible frame structure to facilitate deployment of said device in a delivery catheter.

92. The device of Claim 82 wherein each frame structure includes metal or polymer components.

93. A septal defect closure device, comprising:

a proximal anchor member for deployment proximate a first end of a septal defect;

a distal anchor member for deployment proximate a second end of said septal defect; and

a connecting member connecting said proximal and distal anchor members,

wherein the distal and proximal anchors each comprise a layer that is rolled to form a cylinder during device deployment, and generally flat after deployment.

94. An apparatus for closing a septal defect, comprising:

a delivery system including a sheath having a tip positionable at the defect; and

a septal occluder collapsible for delivery through the sheath for deployment at the septal defect, the septal occluder comprising:

a proximal anchor member for deployment at a first end of the septal defect;

a distal anchor member for deployment at a second end of said septal defect; and

a flexible connection member connecting said proximal and distal anchor members, said proximal and distal anchor members and said connection member comprising bioresorbable materials.

95. An apparatus for closing a septal defect, comprising:

a delivery system including a sheath having a tip positionable at the

defect; and

a septal occluder collapsible for delivery through the sheath for deployment at the septal defect, the septal occluder comprising:

a proximal anchor member having a generally cylindrical shape for deployment at a first end of the septal defect;

a distal anchor member having a generally cylindrical shape for deployment at a second end of said septal defect; and

a suture connecting said proximal and distal anchor members.

96. An apparatus for closing a septal defect, comprising:

a delivery system including a sheath having a tip positionable at the defect; and

a septal occluder collapsible for delivery through the sheath for deployment at the septal defect, the septal occluder comprising:

an elongated proximal anchor member for deployment at a first end of the septal defect;

an elongated distal anchor member for deployment at a second end of said septal defect; and

a flexible layer connecting said proximal and distal anchor members.

97. An apparatus for closing a septal defect, comprising:

a delivery system including a sheath having a tip positionable at the defect; and

a septal occluder collapsible for delivery through the sheath for

deployment at the septal defect, the septal occluder comprising:

a proximal anchor member for deployment at a first end of the septal defect;

a distal anchor member for deployment proximate a second end of said septal defect;

a flexible connection member connecting said proximal and distal anchor members; and

a removal string extending from said proximal anchor member to facilitate collapsing and removal of the occluder from the septal defect into the delivery sheath if desired.

98. The device of Claim 67 wherein said delivery string is attached to the proximal anchor member at a generally central location on the proximal anchor member.

99. The device of Claim 67 wherein said removal string is usable for both removal and deployment of the device.

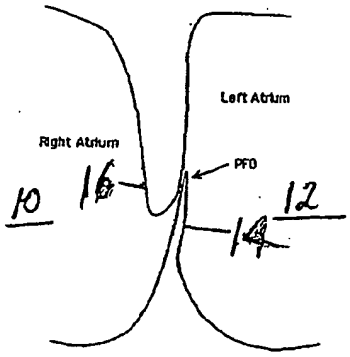


Figure 1

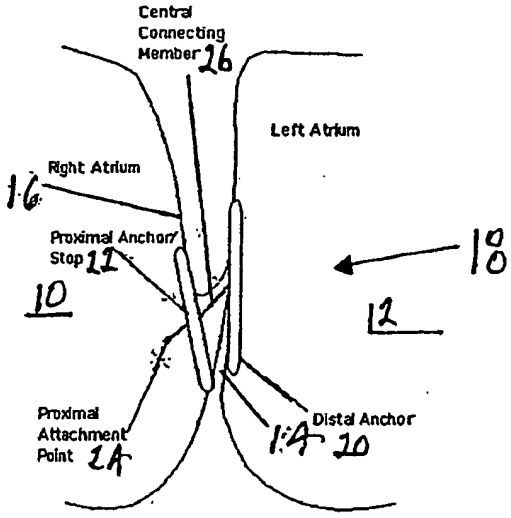


Figure 2

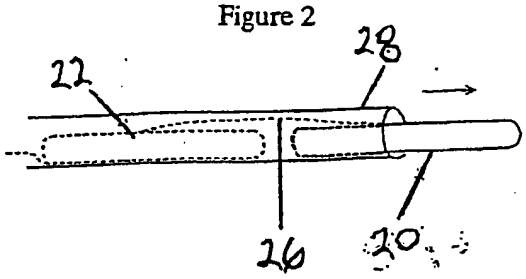


Figure 3

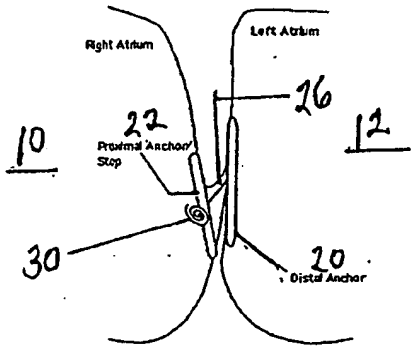


Figure 4

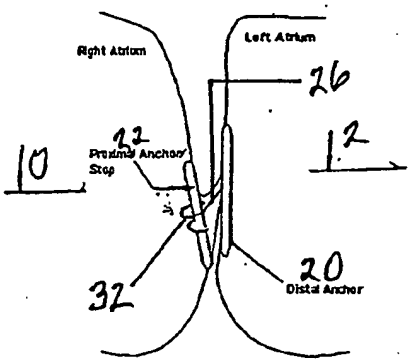


Figure 5

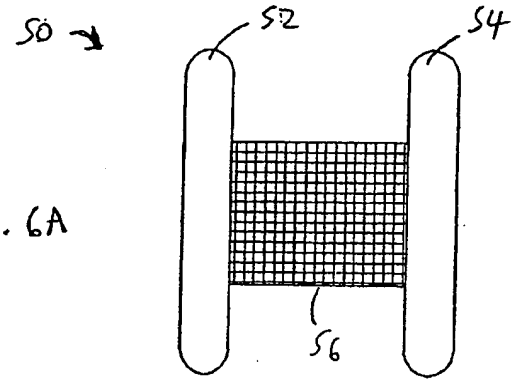


FIG. 6A

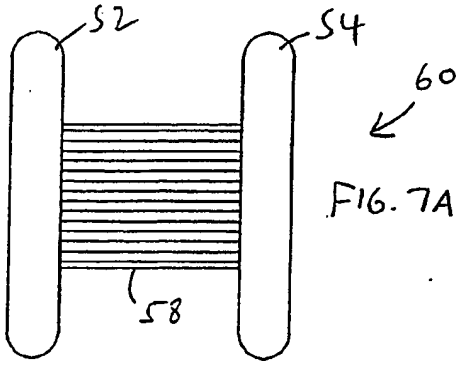


FIG. 7A

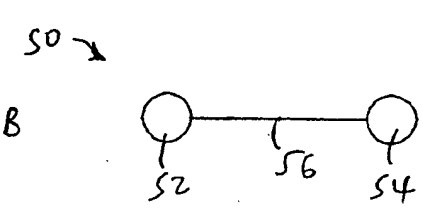


FIG. 6B

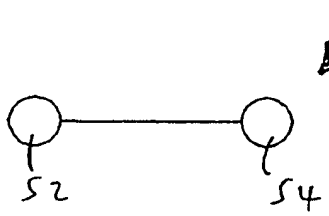


FIG. 7B

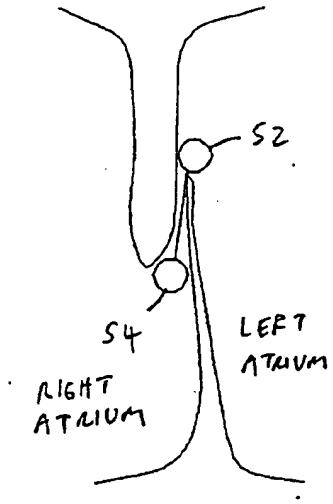


FIG. 8A

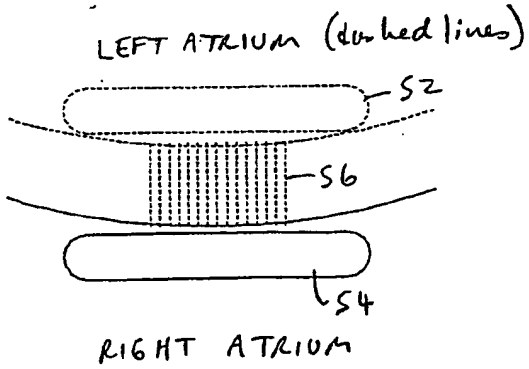
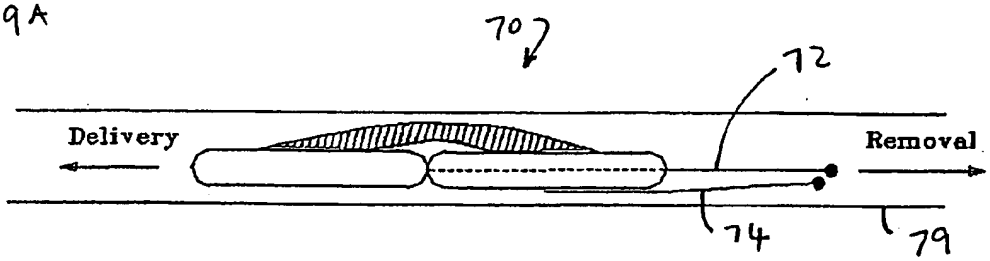


FIG. 8B

FIG. 9A



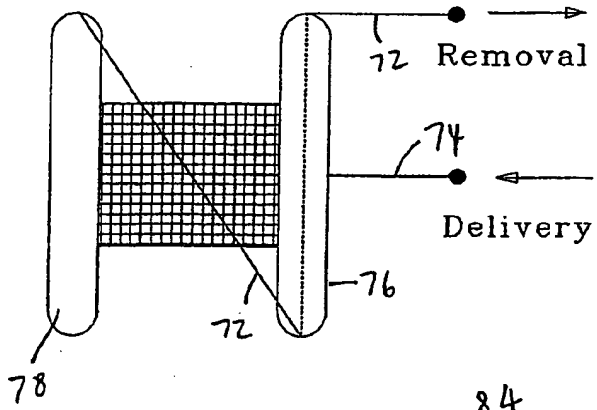


FIG. 9B

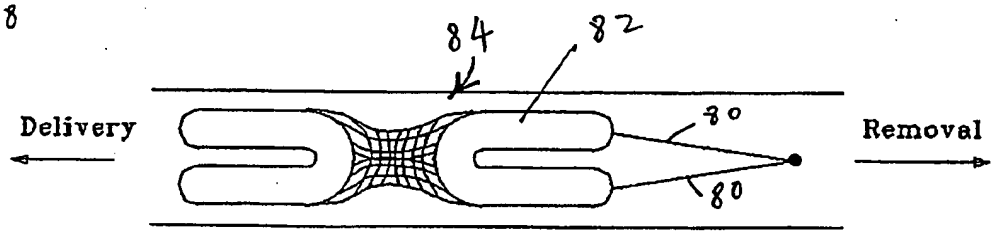


FIG. 10A

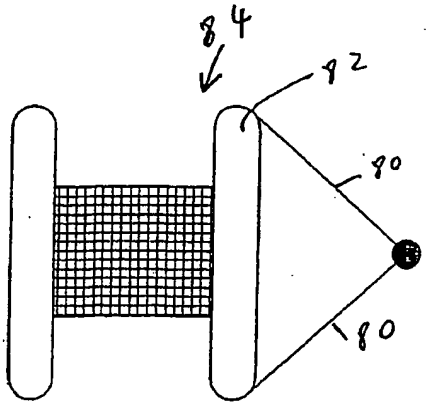
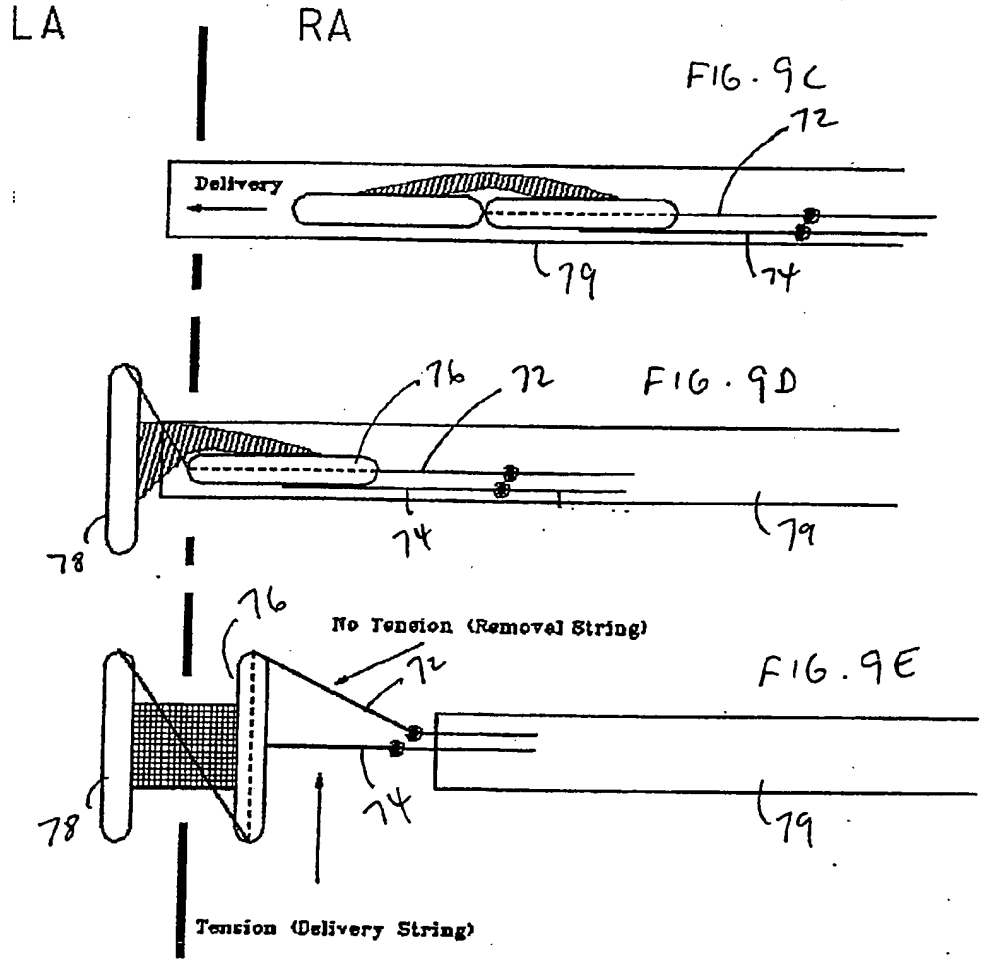
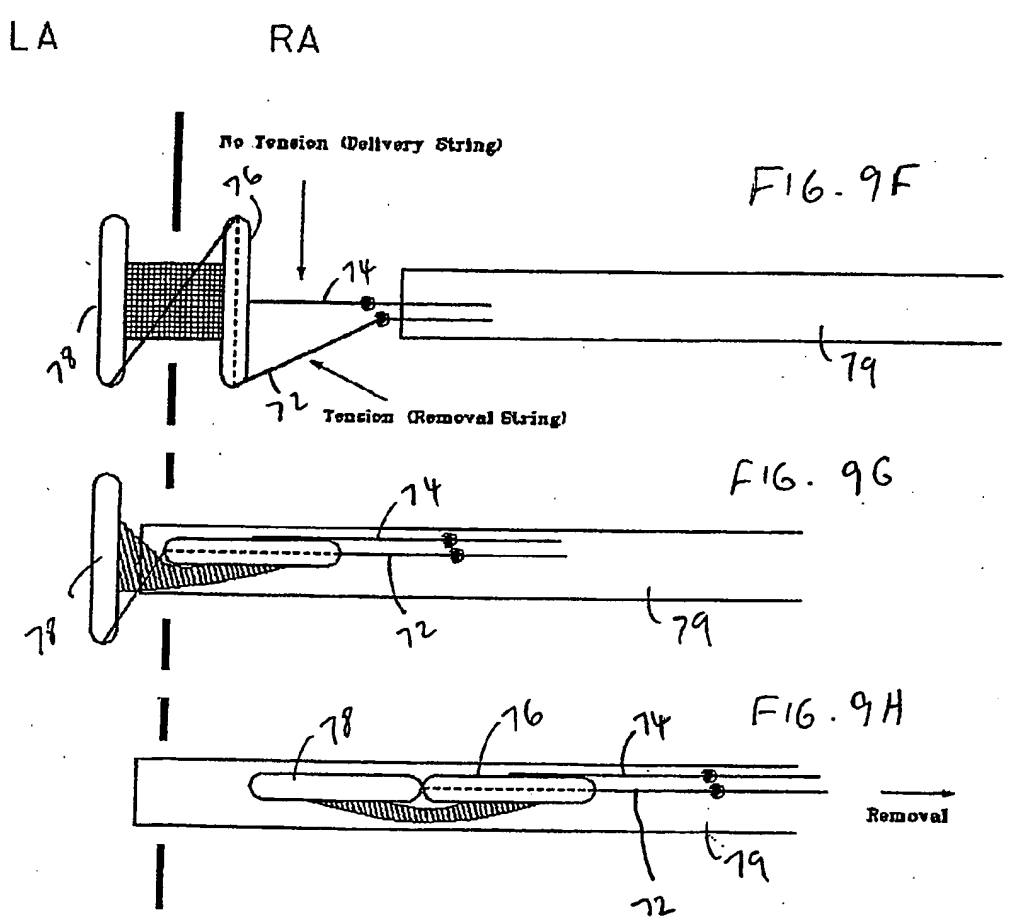


FIG. 10B

Delivery sequence:



Removal sequence:



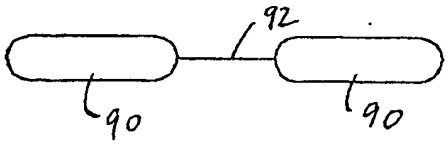


FIG. 11A

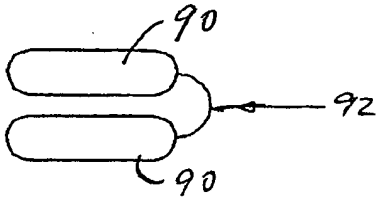


FIG. 11B

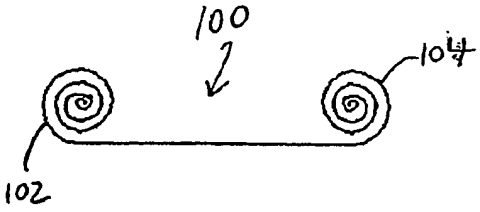


FIG. 12

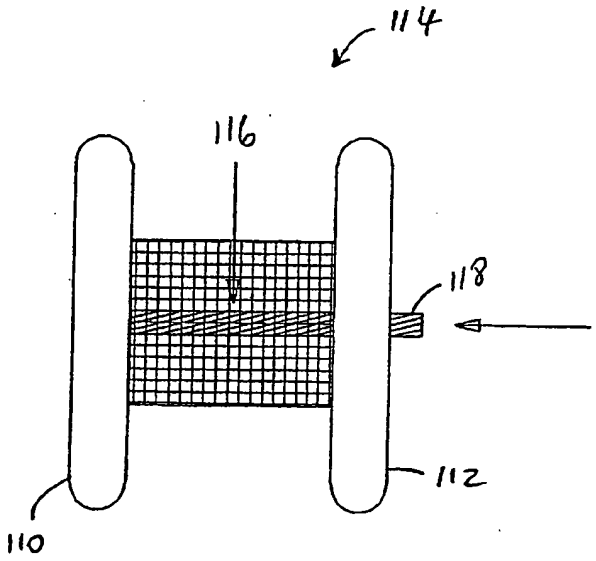


FIG. 13

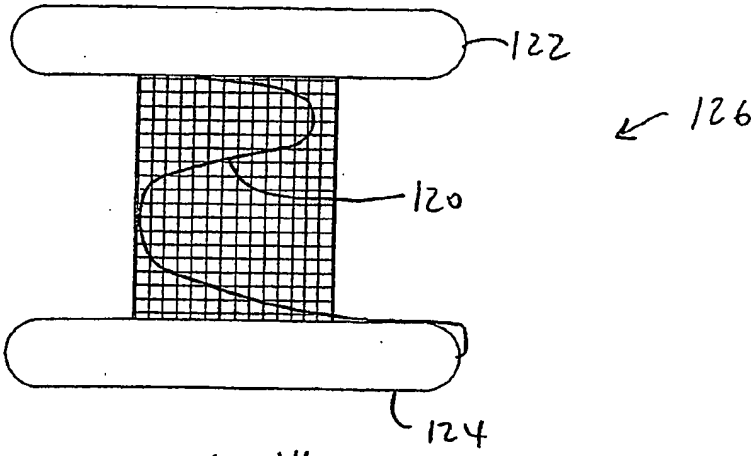


FIG. 14

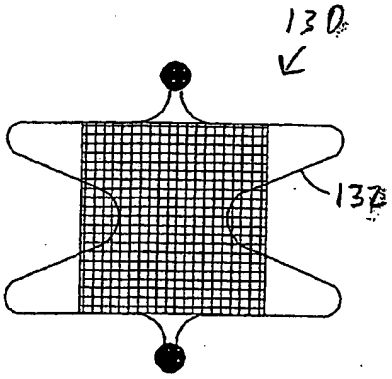


FIG. 15

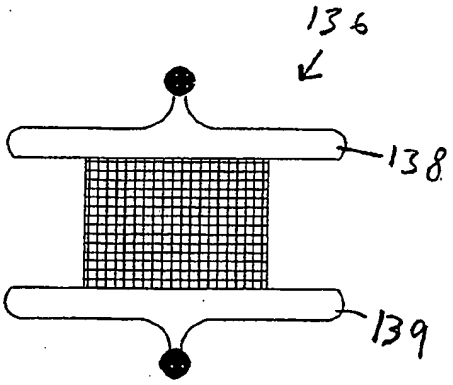


FIG. 16

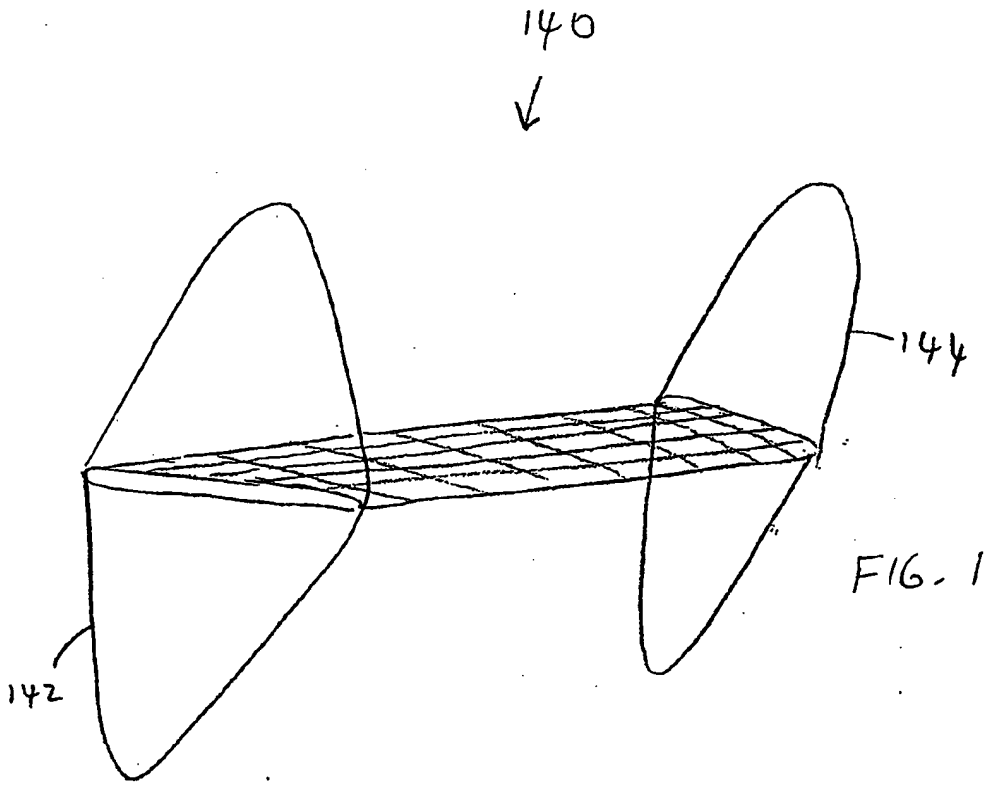


FIG. 17

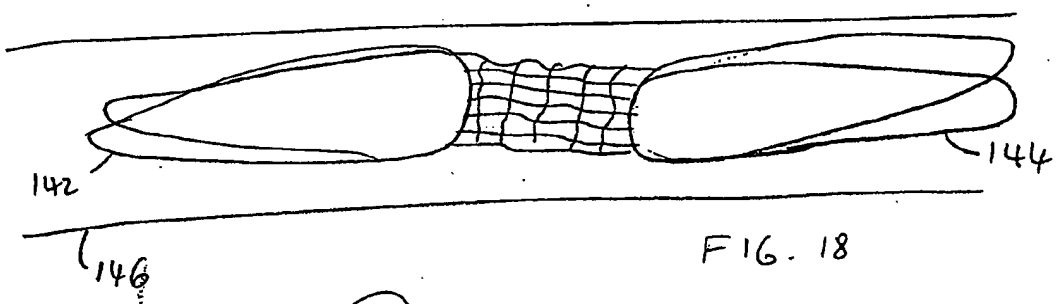


FIG. 18

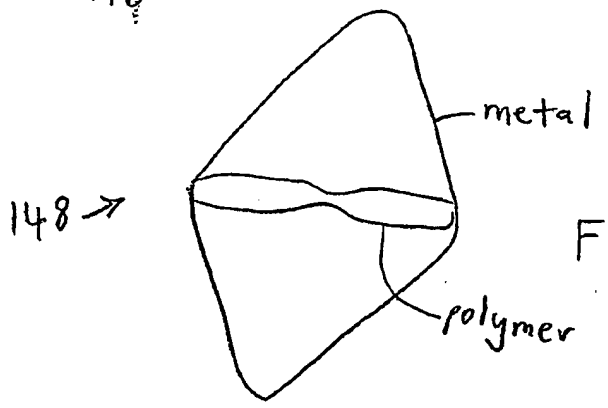


FIG. 19

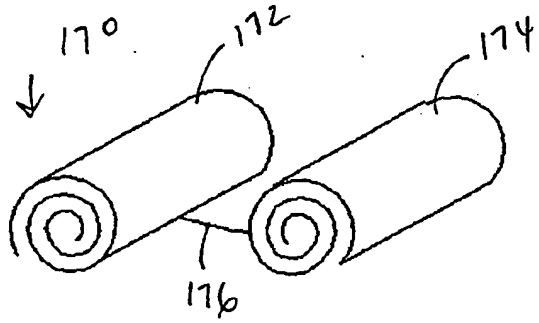


FIG. 20A

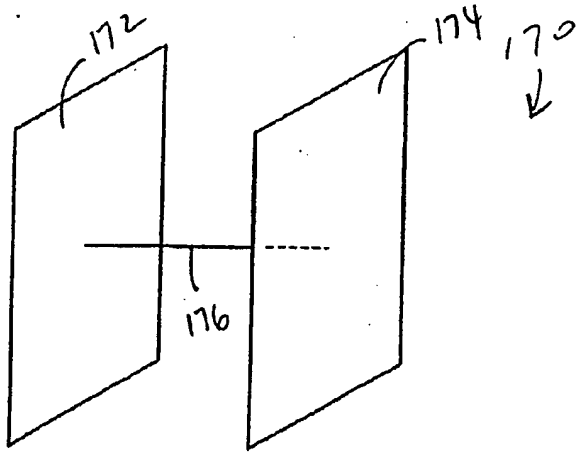


FIG. 20B

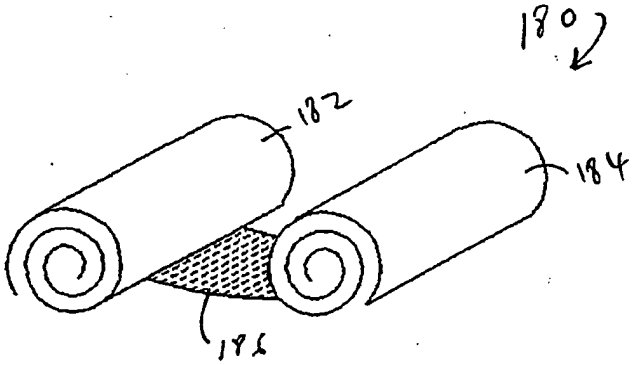


FIG. 21A

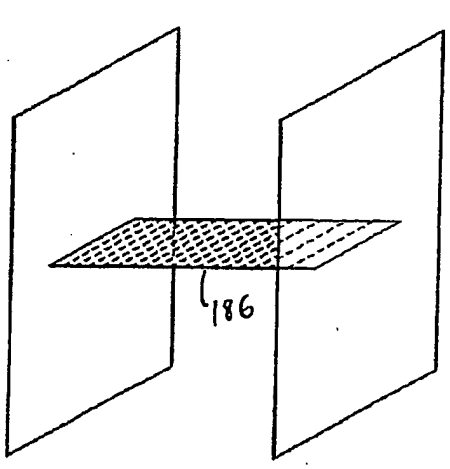
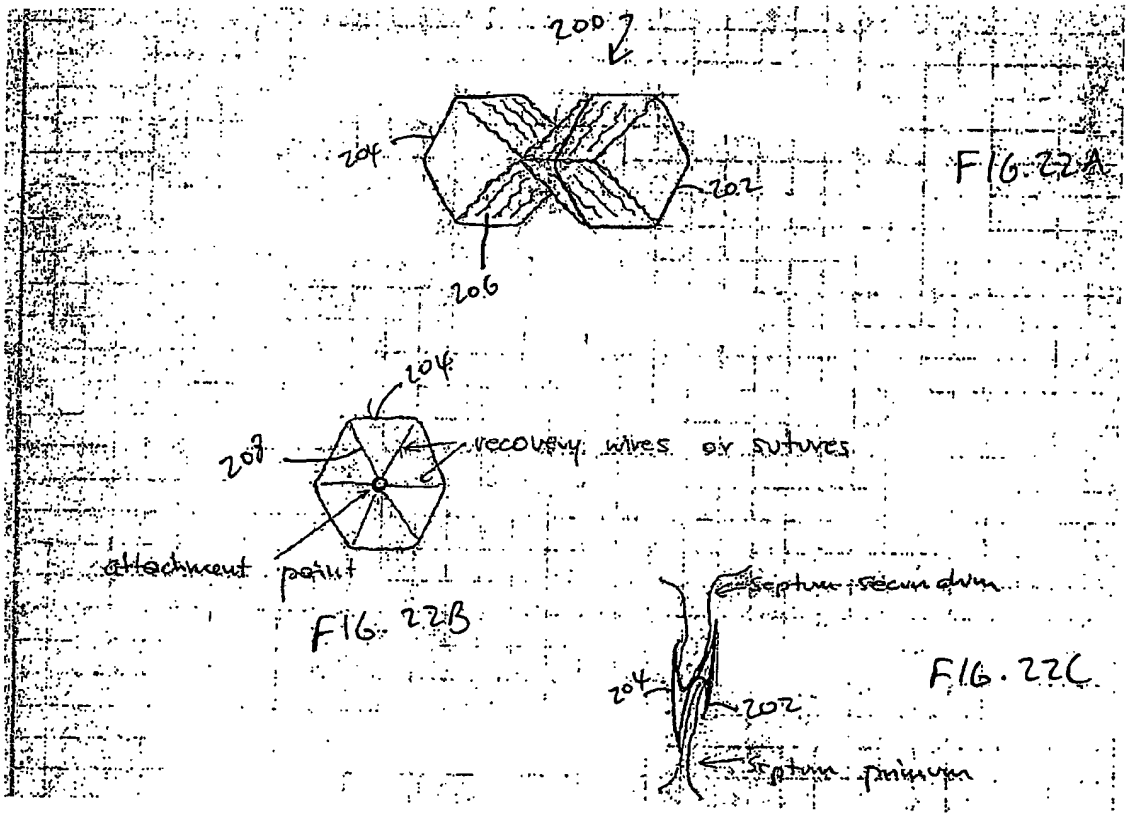


FIG. 21B


200
204
202
206
FIG. 22A
204
208
recovery wires or sutures
attachment point
FIG. 22B
septum secundum
204
202
septum primum
FIG. 22C

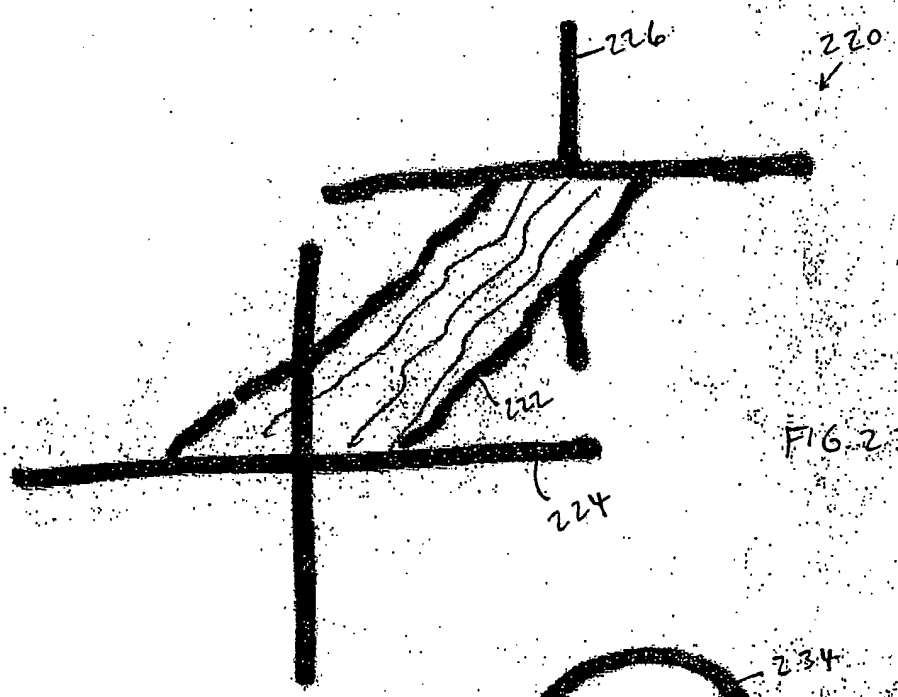


FIG. 23

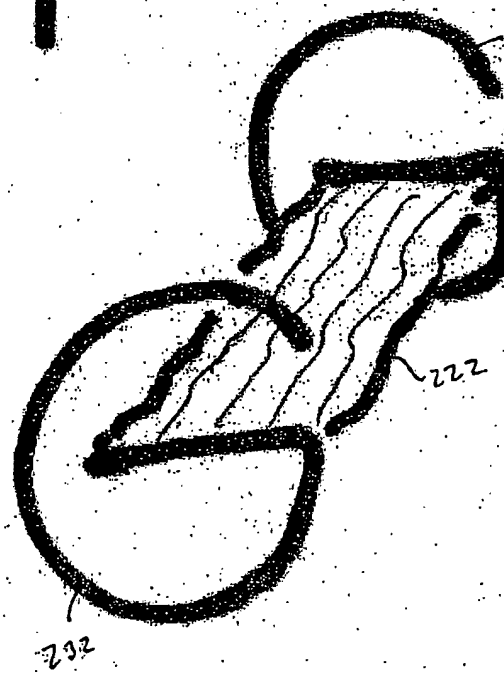


FIG. 24

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US02/40850

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A61B 17/08
US CL : 606/215
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 606/215-217, 213, 232, 151, 157

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6,113,609 A (ADAMS) 05 September 2000, Column 4, lines 17-23, 37-4061-65; Column 5, lines 7-17; Figures 1, 6, 7.	1, 2, 4, 7, 8, 9, 10, 12, 13, 15, 20, 44, 55-58, 63, 94, 96,
X	US 5,861,003 A (LATSON et al.) 19 January 1999, Figures 3 & 6; Column 4, lines 33-65.	44, 46, 49, 52, 55-58, 82, 85-88, 91, 92, 96
---		---
Y		1, 2, 4, 7-10, 12-15, 67, 93, 94,
A, P	US 6,494,888 B1 (LAUFER et al.) 17 December 2002,	
A, P	US 6,387,104 B1 (PUGSLEY, JR. et al.) 14 May 2002.	
Y	US 5,810,884 A (KIM) 22 September 1998; Figures 19-22.	25, 26, 33-35, 38-42
X	US 5,993,475 A (LIN et al.) 30 November 1999; see Abstract, Column 2, lines 25-40, Fig. 2.	1, 44

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 April 2003 (18.04.2003)	19 JUN 2003
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No.	Authorized officer Michael J Milano Diane Smith for Telephone No. (703) 308-1148

Form PCT/ISA/210 (second sheet) (July 1998)

PCT/US02/40850

INTERNATIONAL SEARCH REPORT

C. (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,976,174 A (RUIZ) 02 November 1999; Figures 1B, 2, 4.	44, 96
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Y		94
Y	US 6,077,291 A (DAS) 20 June 2000; Figures 9, 10, 12.	1-4
Y, P	US 6,379,368 B1 (CORCORAN et al.) 30 April 2002; Column 8, lines 13-52.	78-81
X	US 6,214,029 B1 (THILL) 10 April, 2001; Figures 11, 12; Column 3, lines 17-28, Column 5, lines 62-65, Column 9, lines 25-33.	78, 80
X	US 6,206,907 B1 (MARINO et al.) 27 March 2001; Column 6, lines 63-67, Fig. 7.	78

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US02/40850

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claim Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claim Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claim Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest
☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

PCT/US02/40850

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1-77 and 82-99, drawn to a septal occluder .

Group II, claim(s) 78-81, drawn to a process of retrieving a deployed septal occluder.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special inventive feature in Group I is the flexible connection member, whereas the special inventive feature in Group II is the combination of steps in the process of retrieving a deployed septal occluder.